

# FSMA Produce Safety Rule FAQs:

## Qualified Exemption

The Tester-Hagan Amendment was written to provide partial exemptions from FSMA for small producers with direct local sales. Many of Maine's produce farms are eligible for a Qualified Exemption from the Produce Safety Rule if they meet certain direct market sales criteria. Please reach out to us if you have any confusion about whether this applies to you!

### 1. WHAT MAKES A FARM QUALIFIED EXEMPT?

- The Qualified Exemption is one of three coverage status a farm can have. There are three criteria for a farm to be Qualified Exempt.
  - *Your produce sales are over the \$25,000\* threshold.*
  - *Your total food sales are under \$500,000\* cap.*
  - *You are primarily selling to direct markets. (The Rule requires >50% of food sales are going direct to consumer to market channels like farmers markets, restaurants, retail stores, or CSAs.)*

(\*Note: These sales totals are based on the previous 3-years' average and are adjusted for inflation based on 2011 values. See the inflation tables on the **Coverage Page** for the updated values.)

- For more information on the definition of food, produce, and more check out our coverage page or give us a call to talk through your status. Farms that are Qualified Exempt have to meet modified requirements under the Produce Safety Rule.

### 2. WHAT ARE THE MODIFIED REQUIREMENTS?

- There are three requirements for farms that are Qualified Exempt. This means that you do not have to meet the other specific requirements in the Rule like those about worker health and hygiene, water, or buildings. If you are a Qualified Exempt Farm, you need to:
  1. **LABEL YOUR PRODUCTS** with your farm name and full business address:
    - a. *On the food packaging label if the food requires a packaging label.*
    - b. *Prominently and conspicuously at the point of sale if the food does not require a food packaging label. (This can include on signs by the register, on bills of lading, by product displays, on posters, etc.)*
  2. **MAINTAIN SALES RECORDS** that support your **QUALIFIED EXEMPT** status.
  3. **Do an ANNUAL WRITTEN REVIEW & VERIFICATION** that you still meet the **QUALIFIED EXEMPT** eligibility criteria.

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- The annual written review and verification of your Qualified Exempt eligibility does not have to be submitted to the Department of Agriculture, Conservation & Forestry, but you do need to keep it on file for a minimum of 2 years. You also need to keep the sales records you used for the annual review and verification for a minimum of 3 years, since the sales figures are based on a 3-year average.
- Here is [an example](#) of what your written review could look like to satisfy the requirements.

### 3. THAT'S ALL I HAVE TO DO?

- Those are the only specific requirements of the Produce Safety Rule you'll need to meet.
- BUT: you are still required to produce safe food and prevent any potentially adulterated product from entering into commerce. That's required of ALL food businesses in the US under the Federal Food, Drug & Cosmetic Act (FD&C Act). It's a good idea to learn about the basic food safety practices included in the Produce Safety Rule and incorporate as many as you can into your normal operations.

### 4. WILL THE QUALIFIED EXEMPTION GO AWAY AT ANY TIME?

- No, the qualified exemption is written into the rule. It is a long, formal process to open the regulation to make any changes. The only way the qualified exemption would be "taken away" is in the case of a withdrawal of the qualified exemption for an individual farm. This process is outlined in Subpart R of the PSR.

### 5. WHAT COULD MAKE ME LOSE MY FARM'S QUALIFIED EXEMPTION?

- The FDA might withdraw a farm's qualified exemption if one of two things is going on:
  - *If there's an active investigation of a foodborne illness outbreak that is directly linked to your farm.*
  - *If we determine it's necessary in order protect public health based on conditions or conduct associated with your farm that could cause a serious problem.*

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#### **6. SO HOW WOULD THE WITHDRAWAL OF THE QUALIFIED EXEMPTION WORK?**

- There's an entire process that has to happen before a Qualified Exemption is withdrawn. The FDA can consider other actions to protect public health first, like warning letters, recalls, embargoing product, etc.
- The FDA has to notify you in writing of the circumstances or problem that could lead to your farm's Qualified Exemption being withdrawn.
- And the FDA has to consider any actions you take to address those circumstances before they make a decision about withdrawing the Qualified Exemption.
- You can find an overview of the withdrawal process in the **FSMA Facts Presentation**. We recommend you get in touch with us if you are informed that there may be conduct, conditions, or an active foodborne illness outbreak directly linked to your farm that could cause a withdrawal of your Qualified Exemption. We will help explain the process in plain English.

#### **7. IF MY QUALIFIED EXEMPTION IS WITHDRAWN, CAN I GET IT BACK?**

- Yes, you sure can. If issues that caused the withdrawal of the Qualified Exemption are adequately addressed, the FDA can reinstate your Qualified Exempt status. If an active investigation of a foodborne illness outbreak wraps up and determines that your farm was not directly involved, you can also get your Qualified Exemption back. There is also a process where a farm can request the reinstatement of their Qualified Exempt status.

#### **8. WILL I BE INSPECTED IF I'M A QUALIFIED EXEMPT FARM?**

- You definitely can be. Fully covered farms are the inspectional priority, but you're responsible for being ready for inspection by the compliance dates based on farm size.

#### **9. WILL YOU JUST CHECK MY PAPERWORK IF I'M QUALIFIED EXEMPT?**

- Not quite. We will review the modified requirements for Qualified Exempt farms (labeling with farm name and address, maintaining sales records, & annual written verification of QE status).

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- We also are responsible for looking around Qualified Exempt farms to ensure there are no practices or conditions that might result in adulteration or public health risks.

### **10. WHAT HAPPENS IF MY SALES CHANGE AND NOW I'M FULLY COVERED?**

- First, don't panic. There are lots of ways we can help and resources that we can connect you to. You don't have to go it alone. With the Produce Safety Rule being so new there is lots of support for farmers and growers. Contact us at the Department and we will help you.
- The requirements of the Produce Safety Rule are not difficult to get up to speed on, but there are some requirements that are important to flag.
  - *Someone from the farm will have to attend a training, currently the only training that meets the requirements is the Produce Safety Alliance training. [Here](#) are upcoming dates.*
  - *There will be some training requirements for workers on your farm.*
  - *There are some records that are needed for farms that are fully covered. It is not extremely burdensome, but it is something to set up on your farm to make sure you meet your requirements for the Produce Safety Rule.*
- There are other requirements and we can help walk through those with you if you do find your sales increasing or shifting to wholesale markets.

We really do want farms to succeed and continue to thrive in Maine and we are committed to helping you navigate this new regulation. We strive for farms to be confident AND compliant in their food safety measures.